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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,020	10/12/2001	Alan J. Magill	P66822US0 (WRAIR 98-40/46	7596

7590 02/10/2005

Office of the Staff Judge Advocate
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-JA (Ms. Elizabeth Arwine)
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,020	MAGILL ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,11,12,22-25 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,11,12,22-25 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the appeal brief filed on October 26, 2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. Prosecution on the merits of this application is reopened on claims 4, 11, 12, 22-25 and 29-31. The finality of the previous office action is hereby withdrawn. Applicants' response to a final action, under 37 CFR 1.116, received 6/24/2004 has been entered.

3. Claims 4, 11, 12, 22-25 and 29-31 are pending and under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Rejection Withdrawn

5. Rejection of claims 11, 12 and 23 under 35 U.S.C. 102(b), as being anticipated by Leishmania Research Project Do-D-8B or Stitler et al. made in paragraph 10 of the office action mailed 8/26/2003 is withdrawn in view of applicants comments/arguments in the appeal brief.

Double Patenting

6. Applicant is advised that should claim 4 be found allowable, claim 31 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 4 and 31 are identical in scope. Both claims are drawn to a microfluidized Leishmania lysate.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 4, 22, 24, 25 and 29 - 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Leishmania Research project DoD-8B or Stitler et al. (Production of Leishmania Skin Antigen Test GMP Protocol requirements 1 and 2, 1994 and 1995) prior art of record.

Claims are drawn to a microfluidized lysate preparation from a least one Leishmania parasite free of dextran.

Leishmania Research project DoD-8B and Stitler et al teach a microfluidized lysate preparation from Leishmania tropica manufactured in May 1995 (see prior art of record abstract #300, page 186, 44th Annual Meeting of American Society of Tropical Medicine and Hygiene). The prior art teaches the claimed product.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

In the previous responses applicants have argued that all the cited prior art disclose is that first generation lysate preparation and the microfluidized lysate preparation of the present invention is the second generation preparation. The first generation lysates were reformulated in order to prevent hypersensitivity to preparation and that the reformulated preparations were the subject of IND submitted to FDA. Applicants further argued, that the cited prior art do not teach absence of dextran specifically in the reformulated preparation. Applicants further argued that there are several ways to micro fluidize a preparation, including freeze thawing and sonification methods known in the art. The present invention as claimed requires that a slurry of at least one Leishmania parasite strain is microfluidized with a sudden release of pressure.

It is the examiner's position that the claims are drawn to a product by a process. The prior art teaches the claimed product (i.e. Microfluidized lysate from at least one Leishmania parasite). How this product is prepared does not impart any patentability weight on the claimed product. Even applicants in their arguments admitted that there are several ways to microfluidize a preparation, including freeze thawing and sonification methods. Sonification method can also be considered as a method of disrupting the parasite strain with a sudden release of pressure (i.e. mechanical cavitation) through production of extreme sound. Applicants have not provided any

evidence that the argued process limitations provide for any structural difference between the claimed product and the product of the prior art.

The cited prior art teaches the invention as claimed by the applicant. The cited prior art (Project DoD-8B) teaches and has completed both phase I and II of the of development of LSTA. In 1999 the second generation of the lysate was reformulated into a liquid product. There is no recitation that in the cited prior art that the lysate of prior art contains dextran barring evidence to the contrary.

Applicants have also cited an affidavit under 37 CFR 1.132 by Dr. Jonathan B. Berman to over come the rejection. The affidavit is insufficient to overcome the rejection of claims based upon 102 (b) as being anticipated by cited prior art as set forth in the last Office action because:

The examiner has reviewed Dr. Berman's declaration carefully. But the prior art does not recite that the Microfluidized –lysate would contain dextran and Dr. Berman has not submitted evidence in form of laboratory or analytical data that the preparation was tested for the presence of dextran. Therefore, the examiner concludes that the preparation is free of dextran barring evidence to the contrary. Declarant provides no evidence and only opines the position set forth in the response.

Dr. Berman has also argued that the claimed preparation was microfluidized by sudden release of pressure.

It is the examiner's position that the claims are drawn to a product by a process. The prior art teaches the claimed product (i.e. Microfluidized lysate from at least one Leishmania parasite). How this product is prepared does not impart any patentability weight on the claimed product. The purification or production of a product by a particular process does not impart novelty or

unobviousness to a product when the same product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 4, 11, 12, 22-25 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leishmania Research project DoD-8B or Stitler et al. (Production of Leishmania Skin Antigen Test GMP Protocol requirements 1 and 2, 1994 and 1995) prior art of record as applied to claims 4, 22, 24, 25, 29 and 31 above, and further in view of Reed et al. (US 2002/0169285) with a priority date of September 22, 1995 to related U.S. applications.

Claims are drawn to a microfluidized lysate preparation from a least one Leishmania parasite.

Leishmania Research project DoD-8B and Stitler et al teach a microfluidized lysate preparation from Leishmania parasite manufactured in May 1995 (see prior art of record specially abstract #300, page 186, 44th Annual Meeting of American Society of Tropical Medicine and Hygiene). DoD-8B and Stitler et al do not teach implicitly teach different Leishmania strains, a kit, and phenol as a pharmaceutical stabilizer. However, Reed et al. teach different Leishmania species including Leishmania mexicana (see pages 1 and 6), diagnostic skin test (DTH), reagents using pharmaceutically acceptable carriers and preservatives such as phenol

(see page 2, paragraphs 0013-0015 and pages 11and 12) and a diagnostic kit (see claim 22). It would have been *prima facie* obvious to one having ordinary skill in the art to formulate the microfluidzide lysate of DoD-8B or Stitler with the phenol stabilizers of Reed et al. because Reed et al. teach that Leishmania skin test agents are preferably formulated with carriers such as saline and preservatives such as phenol. One of ordinary skill in the art would have been motivated by the teachings of DoD-8B and Stitler that skin tests are widely accepted interventions for diagnosis of prior infection with an infectious agent such as Leishmania to use the microfluidized Leishmania lysate in form of a kit for diagnostic purposes.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

February 6, 2005

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PRIMARY EXAMINER

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